K120485

MAR 16 2012

**510(K) SUMMARY**

**Name and Address of Applicant**
Nihon Kohden America, Inc.
90 Icon Street
Foothill Ranch, CA 92610

**Contact:**
Steve Geerdes
Director, Regulatory Affairs
(949) 580-1555 ex. 3325
Fax: (949) 580-1550

Date: 2/14/2012

**Trade/Device Name:**
Nihon Kohden QP-160AK EEG Trend Program

**Common or usual Name:**
Electroencephalograph (EEG)

**Legally Marketed Predicate:**

Nihon Kohden QP-160AK EEG Trend Program (K092573)

Applied Neuroscience NeuroGuide Analysis System (K041263)

Brain Scope Zoom-100DC (K082886)

**Intended Use:**
The QP-160AK Trend program is a software-only device intended to be installed on the EEG-1200A series electroencephalograph to record, calculate, and display EEG data obtained from the EEG-1200A system. This device is intended to be used by qualified medical practitioners, trained in Electroencephalography, who will exercise professional judgment when using the information.
The intended use for each of the software's outputs is as follows:

- The EEG and aEEG waveforms are intended to help the user monitor the state of the brain.
- The user-defined Fast Fourier Transform (FFT) parameters of this software (FFT power) are intended to help the user analyze the EEG waveform.
- The burst suppression parameters of this software (interburst interval and bursts per minute) are intended to aid in the identification and characterization of areas of burst-suppression pattern in the EEG.

This device does not provide any diagnostic conclusion about the patient's condition to the user.

The device is intended for use by medical personnel in any location within a medical facility, laboratory, clinic or nursing home or outside of a medical facility under direct supervision of a medical professional.

**A summary of the technological characteristics of the device compared to the predicate device:**

The QP-160AK EEG Trend program is the same as the previous version of QP-160AK cleared under 510k but has two new trends available (DSA Asymmetry trend and FFT Power Asymmetry trend).

The QP-160AK EEG Trend program's two new trends (DSA Asymmetry trend and FFT Power Asymmetry trend) are available in the BrainScope Zoom 100 DC (K082886) and the Applied Neuroscience Neuroguide Analysis System (K041263).

**Functional Comparision**

| Nihon Kohden QP -160 Trend program under review | Nihon Kohden QP -160 Trend Program Cleared K092573 | BrainScope Zoom-100DC cleared K082886 | Applied Neuroscience NeuroGuide Analysis System Cleared K041263 |
|---|---|---|---|
| **Function** | | | |
| Number of EEG Channels (Dependant on Amplifier) Up to 32/64 EEG Channels | Same | N/A | N/A |
| Number of DC Channels (Dependant on Amplifier) Up to 8 DC Channels | Same | N/A | N/A |
| Density Spectral Array (DSA) Trend | Same | N/A | N/A |
| Density Spectral Array (DSA) asymmetry Trend | None | Same | Same |
| Spectral Edge Frequency Trend | Same | N/A | N/A |
| Amplitude Integrated EEG (aEEG) Trend | Same | N/A | N/A |
| Burst Suppression Ratio (BSR) Trend | Same | N/A | N/A |
| Inter-burst Interval (IBI) Trend | Same | N/A | N/A |
| Burst Per Minute (BPM) Trend | Same | N/A | N/A |
| FFT Power Trend | Same | N/A | N/A |
| FFT Power Asymmetry Trend | None | Same | Same |
| FFT Power Ratio (e.g. Alpha /Delta, Alpha/Beta) | Same | N/A | N/A |
| External input (DC input) display | Same | N/A | N/A |
| Number of trends More than 16 | Same | N/A | N/A |
| User Selectable Trend Groups (Panel) | Same | N/A | N/A |

| | | | |
|---|---|---|---|
| Time interval of trends<br>1 minute/page to 24 hours /page<br>1 cm/hour to 60 cm/hour | Same | N/A<br><br>N/A | N/A<br><br>N/A |
| User Selectable Trends Time Scale | Same | N/A | N/A |
| Annotation list | Same | N/A | N/A |
| Raw EEG data display<br>Look-Back while recording<br>Synchronized Video | Same | N/A | N/A |

**Testing (Non Clinical & Clinical)**

- To date no special controls or performance standards are known or established for this device as required by sections 513(b) and 514 of the Food, Drug and Cosmetic Act as implemented by 21 CFR Part 861.

- The device is not sterile.

- The device does not directly contact patients. Therefore, good laboratory practice studies were not required per 21 CFR Part 58.

- The QP-160AK EEG Trend Program was subjected to safety and performance testing procedures. The QP-160AK EEG Trend Program has undergone validation and verification testing to ensure conformance to all design requirements. Additionally, the system has undergone comparison testing to ensure the substantial equivalence of the calculation and display of EEG trends. These tests verified that the device performed within specifications.

- No Clinical testing was required

**Conclusion of Substantial Equivalence:**

- The comparison of technological characteristics and performance testing of the QP-160AK EEG Trend Program demonstrate that its safety, effectiveness, and performance are equivalent to the specified predicate devices.
- This software device is exactly the same as the predicate QP-160AK (K092573) except for the addition of the two trends (DSA Asymmetry trend and FFT Power Asymmetry trend) that were added to the new QP-160AK. The Brainscope-100DC and the Applied Neuroscience Neuroguide Analysis System (K041263) provide the same DSA Asymmetry trend and FFT Power Asymmetry trend as the new QP-160AK. Therefore, Nihon Kohden believes that the device is substantially equivalent to the stated predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 16 2012

Nihon Kohden America, Inc.
c/o Steve Geerdes
Director, Regulatory Affairs
90 Icon Street
Foothill Ranch, CA 92610

Re: K120485
Trade/Device Name: Nihon Kohden QP-160AK EEG Trend Program
Regulation Number: 21 CFR 882.1400
Regulation Name: Amplitude-integrated electroencephalograph
Regulatory Class: Class II
Product Code: OMA, OLT, ORT
Dated: February 14, 2012
Received: February 17, 2012

Dear Mr. Geerdes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use Form

510(k) Number (if known): K120485

Device Name: ___ Nihon Kohden QP-160AK Trend Program with the addition of DSA Asymmetry trend and FFT Power Asymmetry trend

Indications for Use:

The QP-160AK Trend program is a software-only device intended to be installed on the EEG-1200A series electroencephalograph to record, calculate, and display EEG data obtained from the EEG-1200A system. This device is intended to be used by qualified medical practitioners, trained in Electroencephalography, who will exercise professional judgment when using the information.

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This device does not provide any diagnostic conclusion about the patient's condition to the user.

The device is intended for use by medical personnel in any location within a medical facility, laboratory, clinic or nursing home or outside of a medical facility under direct supervision of a medical professional.

Prescription Use ____X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices



510(k) Number K120485